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STEMI-patients’ Considerations And Attitudes Towards Participation In Randomized Clinical Trials(RCT)

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Background

RCT in the setting of STEMI is necessary and important.

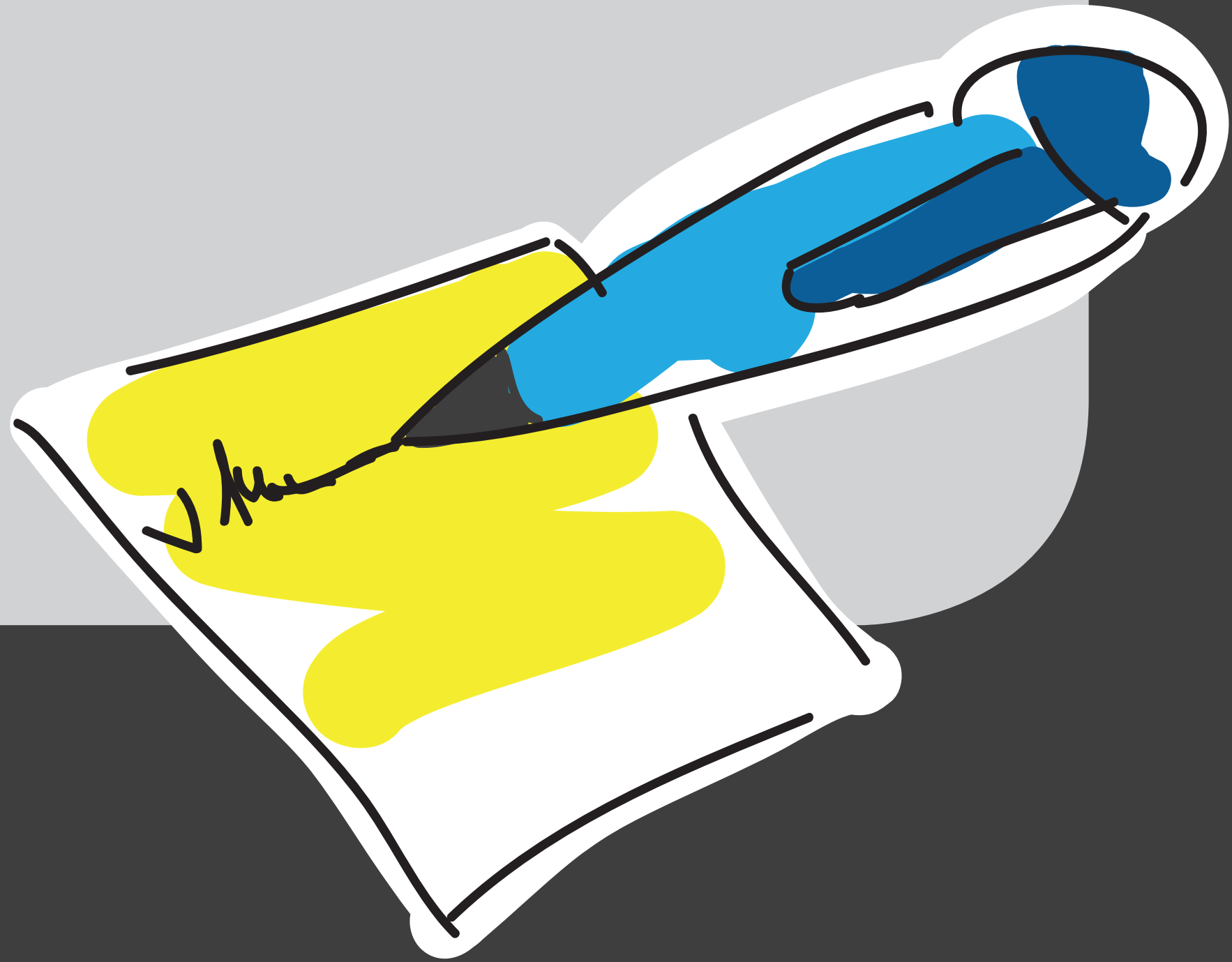
A STEMI-patient is considered a “Vulnerable Subject” due to the emergency of the situation. The patient might feel:

- it is a stressful situation
- fear of dying
- pain
- anxiety
- nausea
- separation from loved ones



Methods and Material

- STEMI-patients asked to consider participation in RCT in the Cath.Lab.
- Semi-quantitative questionnaire
- Anonymous
- 24/7
- 6-48 hours after PPCI (in-hospital)
- 100 study subjects



Hypothesis

- The STEMI-patient feels pressured to participate in RCT
- The STEMI-patient is unable to understand the information about participating in RCT because of the stressful situation

Purpose

- To understand to which extent the STEMI-patient feels able to consider participation in RCT, and what has influence on this decision



Results

- 96% (96/100) answered the questionnaires
- 94% (94/100) accepted inclusion in RCT
- 78% (69/88) understood information on an acceptable or satisfactory level
- 83% (75/90) participated in RCT to help Clinical Research
- 85% (79/93) are positive about future participation in RCT
- 51% (46/90) state correct the number of RCT in which they participated
- 22% (20/90) underestimated the number of RCT in which they participated
- 9% (8/90) did not know they actually participated in RCT

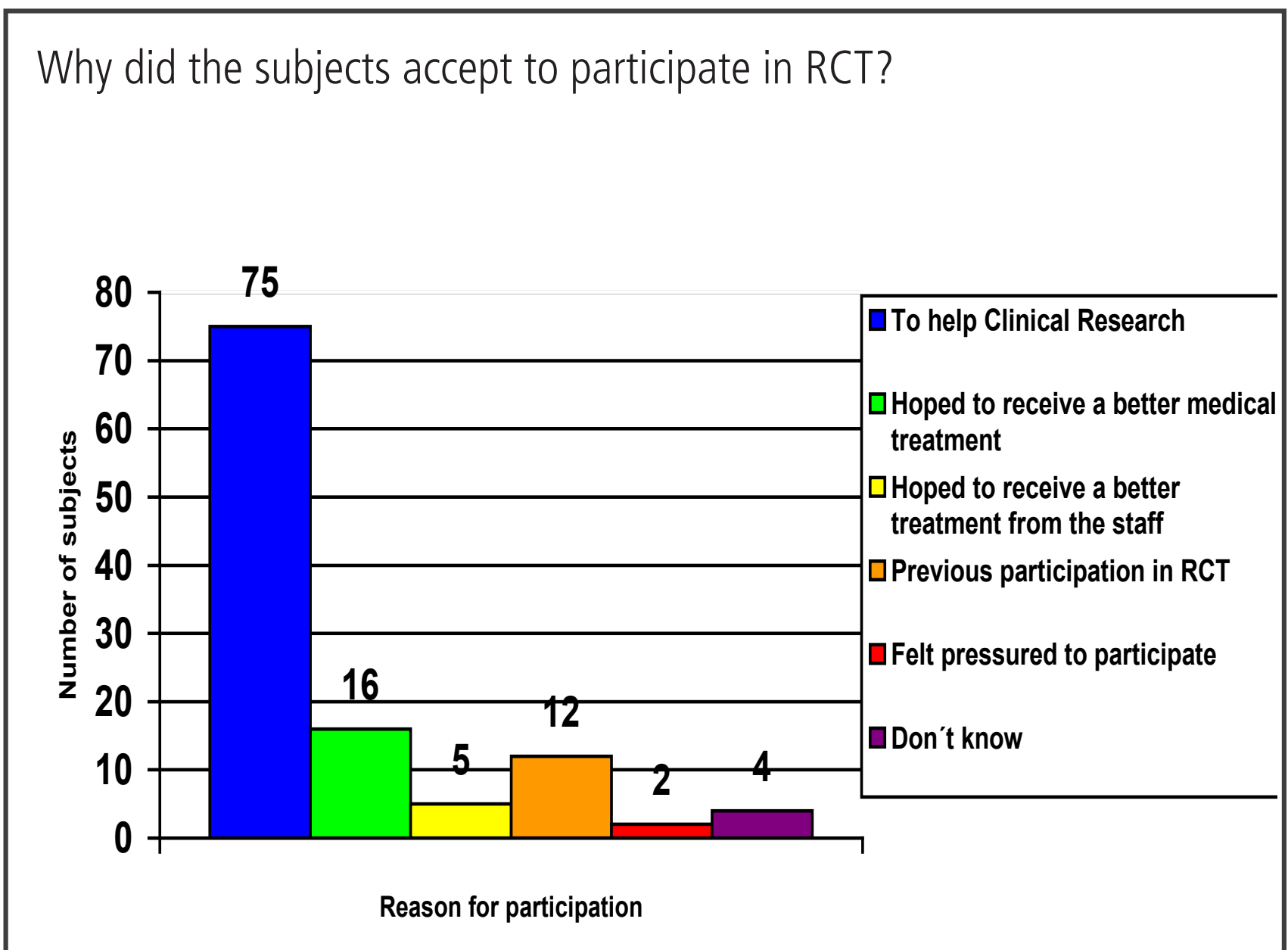
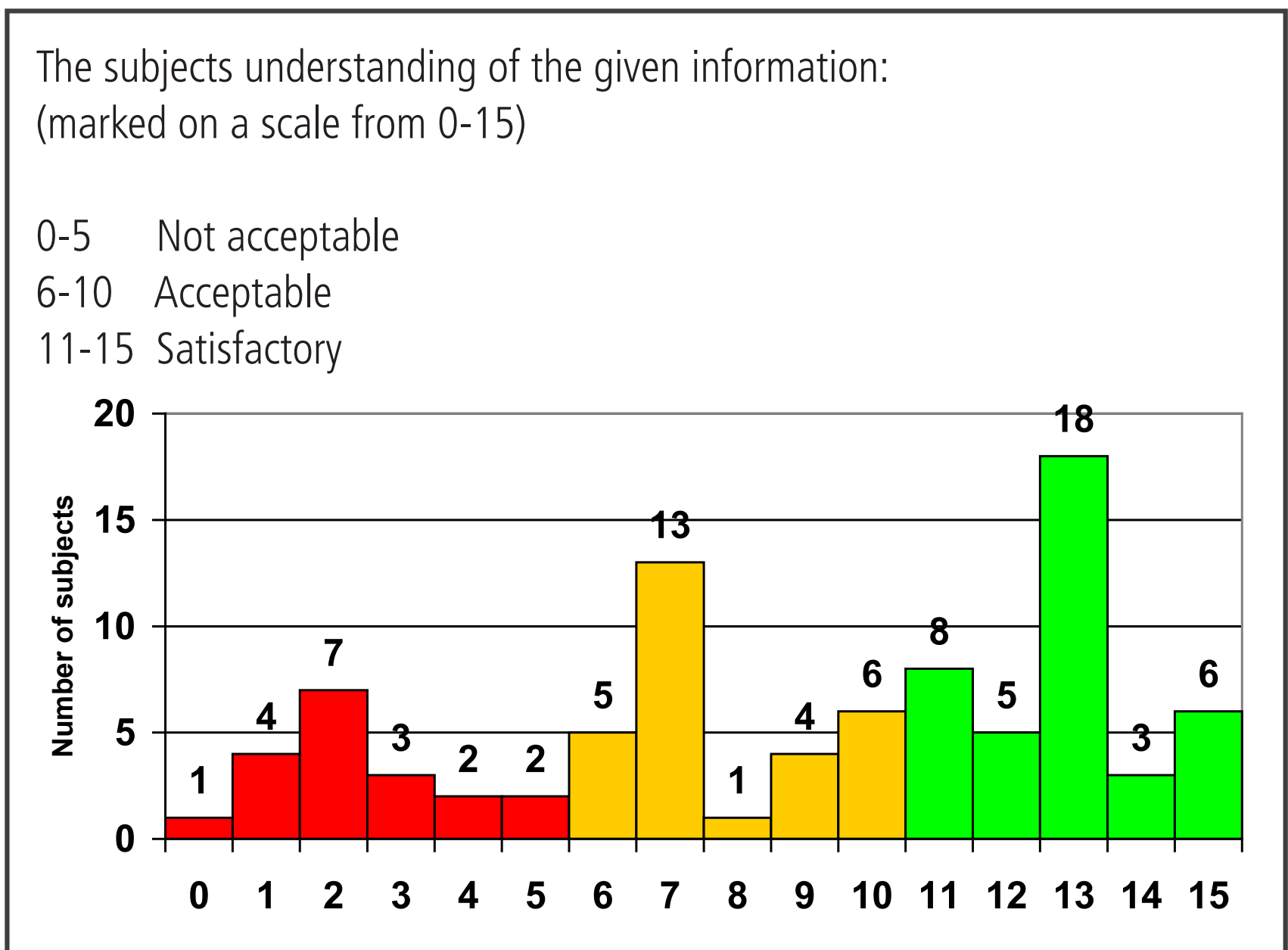
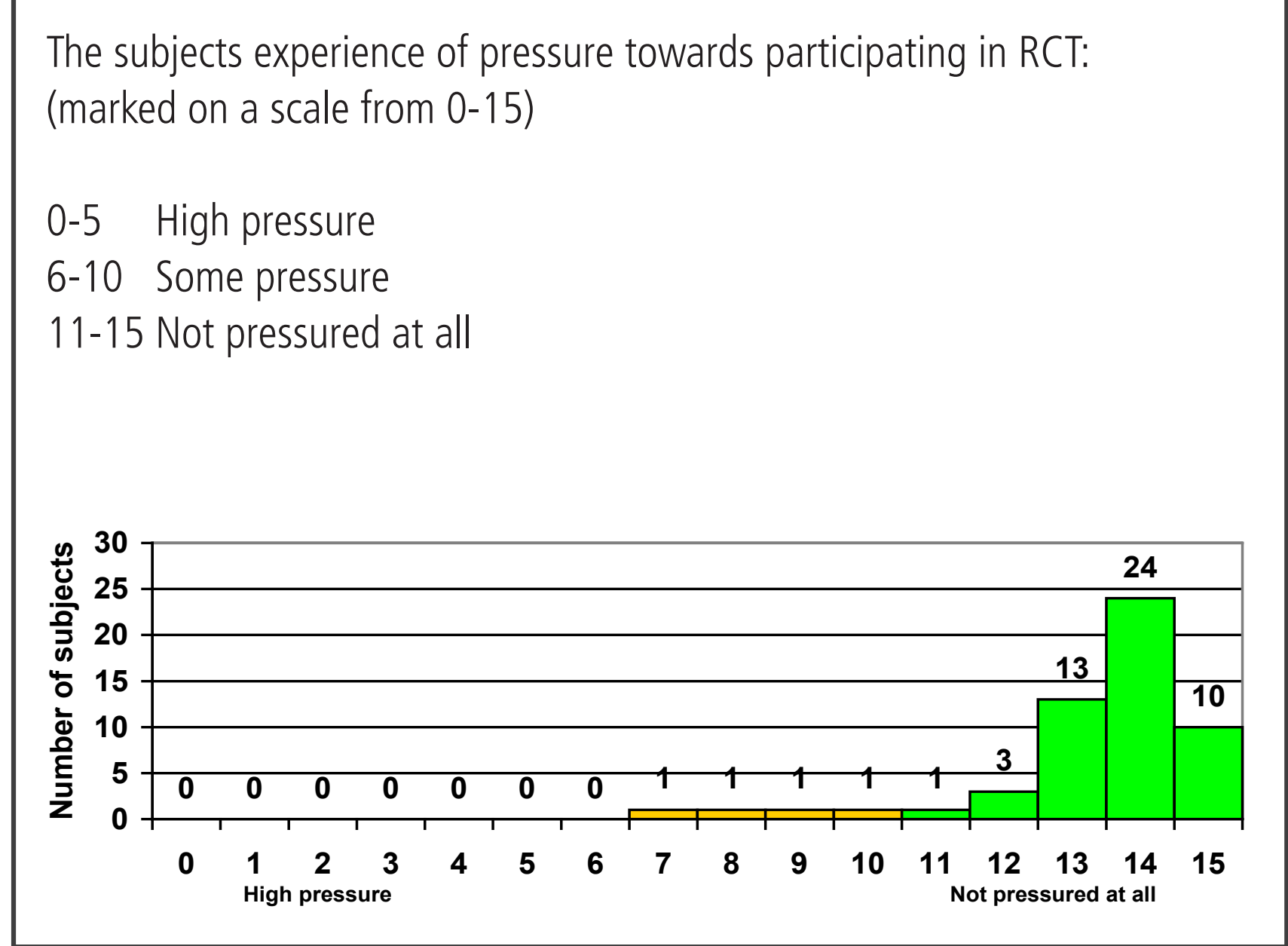


Patient’s comments

- “I feel obligated to help Clinical Research”
- “I didn’t dare gamble with my life”
- “It was a stressful situation, but it could not be any different, OK.”
- “I had a lot of pain and didn’t care”
- “It happened so fast and I wanted to start treatment immediately”

Conclusion

1. The subjects did not experience pressure to participate in RCT
2. The subjects claimed to understand the given information about RCT on an acceptable or satisfactory level. However only 51% of the participating subjects correctly stated the number of RCT in which they actually participated
3. The subjects participated in RCT primarily to help Clinical Research
4. The subjects are willing to participate in RCT in the future



Limitation

Only a limited number of subjects participated in present study

Future

A larger scale study is planned in order to obtain statistical power